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| <b>THIRD SUPPLEMENTAL<br/>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(Use as many sheets as necessary) |   | <b>Complete if Known</b> |                      |                        |                      |
|  |   | Application Number       | 10/725,015           |                        |                      |
|  |   | Filing Date              | December 2, 2003     |                        |                      |
|  |   | First Named Inventor     | GEALL, Andrew        |                        |                      |
|  |   | Art Unit                 | 1635                 |                        |                      |
|  |   | Examiner Name            | SCHNIZER, Richard A. |                        |                      |
| Sheet  | 1 | of                       | 4                    | Attorney Docket Number | 1530.0610001/EJH/UWJ |

| NON PATENT LITERATURE DOCUMENTS |                          |  |                |
|---------------------------------|--------------------------|--|----------------|
| Examiner<br>Initials*           | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published         | T <sup>2</sup> |
| BS                              | NPL1                     | BAUMGARTNER, I., et al., "Constitutive Expression of phVEGF <sub>165</sub> After Intramuscular Gene Transfer Promotes Collateral Vessel Development in Patients With Critical Limb Ischemia," <i>Circulation</i> 97:1114-1123, American Heart Association, Inc. (1998) |                |
|                                 | NPL2                     | CHEN, Z.Y., et al., "Linear DNAs Concatemerize <i>in Vivo</i> and Result in Sustained Transgene Expression in Mouse Liver," <i>Mol. Ther.</i> 3:403-410, The American Society of Gene Therapy (2001)   |                |
|                                 | NPL3                     | CHENG, S.H., and SCHEULE, R.K., "Airway delivery of cationic lipid: DNA complexes for cystic fibrosis," <i>Adv. Drug Deliv. Rev.</i> 30:173-184, Elsevier Science B.V. (1998)  |                |
|                                 | NPL4                     | CHERNG, J.-Y., et al., "Effect of DNA topology on the transfection efficiency of poly((2-dimethylamino)ethyl methacrylate)-plasmid complexes," <i>J. Control. Release</i> 60:343-353, Elsevier Science B.V. (1999)   |                |
|                                 | NPL5                     | CHERNG, J.-Y., et al., "Stabilization of polymer-based gene delivery systems," <i>Intl. J. Pharm.</i> 183:25-28, Elsevier Science B.V. (1999)  |                |
|                                 | NPL6                     | CORVELEYN, S, and REMON, J.P., "Maltodextrins as Lyoprotectants in the Lyophilization of a Model Protein, LDH," <i>Pharm. Res.</i> 13:146-150, Plenum Publishing Corporation (1996)  |                |
|                                 | NPL7                     | DALESANDRO, J., et al., "Gene Therapy for Donor Hearts: Ex Vivo Liposome-Mediated Transfection," <i>J. Thorac. Cardiovasc. Surg.</i> 111:416-422, Mosby-Year Book, Inc. (1996)   |                |
|                                 | NPL8                     | DANKO, I., et al., "Dystrophin expression improves myofiber survival in <i>mdx</i> muscle following intramuscular plasmid DNA injection," <i>Hum. Mol. Genet.</i> 2:2055-2061, Oxford University Press (1993)  |                |
|                                 | NPL9                     | DARQUET, A.-M., et al., "A new DNA vehicle for nonviral gene delivery: supercoiled minicircle," <i>Gene Ther.</i> 4:1341-1349, Stockton Press (1997)   |                |
|                                 | NPL10                    | DAVIS, H.L., et al., "Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen," <i>Vaccine</i> 12:1503-1509, L.R. Printing Services Ltd. (1994)  |                |

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|                                 | NPL11                 | DOW, S.W., <i>et al.</i> , "Systemic and Local Interferon $\gamma$ Gene Delivery to the Lungs for Treatment of Allergen-Induced Airway Hyperresponsiveness in Mice," <i>Hum. Gene Ther.</i> 10:1905-1914, Mary Ann Liebert, Inc. (1999)               |                |
|                                 | NPL12                 | GRAMZINSKI, R., <i>et al.</i> , "Immune Response to a Hepatitis B DNA Vaccine in Aotus Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Mol. Med.</i> 4:109-118, The Picower Institute Press (1998)             |                |
|                                 | NPL13                 | HARLAND, R., and MISHER, L., "Stability of RNA in developing <i>Xenopus</i> embryos and identification of a destabilizing sequence in TFIIA messenger RNA," <i>Development</i> 102:837-852, The Company of Biologists Limited (1988)                  |                |
|                                 | NPL14                 | HORTON, H.M., <i>et al.</i> , "A gene therapy for cancer using intramuscular injection of plasmid DNA encoding interferon $\alpha$ ," <i>Proc. Natl. Acad. Sci. USA</i> 96:1553-1558, National Academy of Sciences (1999)                             |                |
|                                 | NPL15                 | KIM, A.I., <i>et al.</i> , "The Physical State of Mannitol after Freeze-Drying: Effects of Mannitol Concentration, Freezing Rate, and a Noncrystallizing Cosolute," <i>J. Pharm. Sci.</i> 87:931-935, American Chemical Society (1998)                |                |
|                                 | NPL16                 | LEVY, M.Y., <i>et al.</i> , "Characterization of plasmid DNA transfer into mouse skeletal muscle: evaluation of uptake mechanism, expression and secretion of gene products into blood," <i>Gene Ther.</i> 3:201-211, Stockton Press (1996)           |                |
|                                 | NPL17                 | MARTINI, A., <i>et al.</i> , "Use of subambient differential scanning calorimetry to monitor the frozen-state behavior of blends of excipients for freeze-drying," <i>PDA J. Pharm. Sci. Tech.</i> 51:62-67, PDA, Inc. (1997)                         |                |
|                                 | NPL18                 | MARTINI, A., <i>et al.</i> , "Use of subambient differential scanning calorimetry to monitor the frozen state behaviour of amino acids in simulated freeze-drying conditions," <i>STP Pharma. Sci.</i> 7:377-381, STP Pharma Sciences (1997)          |                |
|                                 | NPL19                 | MIR, L.M., <i>et al.</i> , "High-efficiency gene transfer into skeletal muscle mediated by electric pulses," <i>Proc. Natl. Acad. Sci. USA</i> 96:4262-4267, National Academy of Sciences (1999)  |                |
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|                                 | NPL21                 | MOLINA, M.C. <i>et al.</i> , "Maintenance of nonviral vector particle size during the freezing step of the lyophilization process is insufficient for preservation of activity: insight from other structural indicators." <i>J. Pharma. Sci.</i> 90:1445-1455, Wiley-Liss, Inc (October 2001) |                |
|                                 | NPL22                 | NOVO, F.J., <i>et al.</i> , "Gene transfer and expression of human $\alpha$ -galactosidase from mouse muscle in vitro and in vivo," <i>Gene Ther.</i> 4:488-492, Stockton Press (1997)   |                |
|                                 | NPL23                 | OLIYAI, C., <i>et al.</i> , "Chemical Pathways of Peptide Degradation. VII. Solid State Chemical Instability of an Aspartyl Residue in a Model Hexapeptide," <i>Pharma. Res.</i> 11:901-908, Plenum Publishing Corporation (1994)  |                |
|                                 | NPL24                 | ORIZIO, G., <i>et al.</i> , "Freeze-dried mannitol for injectable preparations using an automatic lyophilization cycle," <i>Boll. Chim. Farmaceutico</i> 132:368-374, Società Editoriale Farmaceutica (1993)   |                |
|                                 | NPL25                 | ÖSTERBERG, T., <i>et al.</i> , "Development of a Freeze-Dried Albumin-Free Formulation of Recombinant Factor VIII SQ," <i>Pharma. Res.</i> 14:892-898, Plenum Publishing Corporation (1997)  |                |
|                                 | NPL26                 | PELLETIER, J., and SONENBERG, N., "Internal initiation of translation of eukaryotic mRNA directed by a sequence derived from poliovirus RNA," <i>Nature</i> 334:320-325, Macmillan Magazines Ltd. (1988)   |                |
|                                 | NPL27                 | PICCIRILLO, C.A., and PRUD'HOMME, G.J., "Prevention of Experimental Allergic Encephalomyelitis by Intramuscular Gene Transfer with Cytokine-Encoding Plasmid Vectors," <i>Hum. Gene Ther.</i> 10:1915-1922, Mary Ann Liebert, Inc. (1999)  |                |
|                                 | NPL28                 | PICCIRILLO, C.A., <i>et al.</i> , "TGF- $\beta$ 1 Somatic Gene Therapy Prevents Autoimmune Disease in Nonobese Diabetic Mice," <i>J. Immunol.</i> 161:3950-3956, The American Association of Immunologists (1998)  |                |
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| ✓                               | NPL30                 | QIN, Y.-J., <i>et al.</i> , "Gene Suture - A Novel Method for Intramuscular Gene Transfer and its Application in Hypertension Therapy," <i>Life Sci.</i> 65:2193-2203, Elsevier Science Inc. (1999)  |                |

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|                                 | NPL31                 | RAGNO, S., <i>et al.</i> , "Protection of Rats from Adjuvant Arthritis by Immunization with Naked DNA Encoding for Mycobacterial Heat Shock Protein 65," <i>Arthritis Rheum.</i> 40:277-283, American College of Rheumatology (1997)                      |                |
|                                 | NPL32                 | RESTIFO, N.P., <i>et al.</i> , "Enhancing the Recognition of Tumour Associated Antigens," <i>Folia Biologica</i> 40:74-88, Institute of Molecular Genetics (1994)   |                |
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|                                 | NPL34                 | TRIPATHY, S.K., <i>et al.</i> , "Long-term expression of erythropoietin in the systemic circulation of mice after intramuscular injection of a plasmid DNA vector," <i>Proc. Natl. Acad. Sci. USA</i> 93:10876-10880, National Academy of Sciences (1996) |                |
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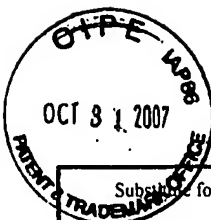
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| Examiner Initials*    | Cite No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear |
|                       |                       | Number-Kind Code <sup>2</sup> (if known) |                                |  |   |
| VJ                    | US1                   | 5,641,665                                | 06/24/1997                     | Hobart <i>et al.</i>                               |   |
|                       | US2                   | 5,679,354                                | 10/21/1997                     | Morein <i>et al.</i>                               |   |
|                       | US3                   | 5,703,055                                | 12/30/1997                     | Felgner <i>et al.</i>                              |   |
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|                       | US11                  | 2004/0162256 A1                          | 08/19/2004                     | Geall <i>et al.</i>                                |   |
|                       | US12                  | 2005/0065107 A1                          | 03/24/2005                     | Hobart <i>et al.</i>                               |   |
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|                       | US14                  | 2006/0134221 A1                          | 06/22/2006                     | Geall, A.  |   |
|                       | US15                  | 2007/0105193 A1                          | 05/10/2007                     | Vilalta <i>et al.</i>                              |   |
|                       | US16                  | 2007/0105799 A1                          | 05/10/2007                     | Hermanson, G.G.                                    |   |
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|                          |                       | Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known) |                                |  |   |                |
| VJ                       | FPI                   | WO 2001/065911 A2   | 09/13/2001                     | Valentis, Inc.                                     |   |                |
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